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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/498,098	02/04/2000	Jeffrey Stack	AURO1330	8316

7590 08/28/2006

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EXAMINER	
ANGELL, JON E	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 08/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/498,098	STACK ET AL.	
	Examiner	Art Unit	
	Jon Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9,11-31,34-38,50,55 and 60* is/are pending in the application.

4a) Of the above claim(s) *55* is/are withdrawn from consideration.

5)☒ Claim(s) *38,50 and 60* is/are allowed.

6)☒ Claim(s) *1-6,9,11-31 and 34-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Action is in response to the communication filed on 6/7/2006.

The amendment filed 6/7/2006 is acknowledged and has been entered.

Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Status of the Claims

Claims 1-6, 9, 11-31, 34-38, 50, 55, 60 are currently pending in the application and are addressed herein.

Claim 55 has been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 7/2/2001.

Claims 1-6, 9, 11-31, 34-38, 50 and 60 are examined herein

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 9, 11-31 and 34-37 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 1 and 23 have been amended such that they are now drawn to an in vitro method comprising providing a cell comprising a polynucleotide molecule comprising a destabilization domain a linker moiety and either a target or reporter moiety. However, the destabilization domain, linker moiety and target/reporter moiety are all polypeptide elements. Polynucleotides are comprised of nucleic acids while polypeptides are comprised amino acids. Therefore claims 1, 23, as well as all claims that depend therefrom are indefinite because it is not clear how a polynucleotide molecule can comprise peptide elements.

It is noted that amending the claims to indicate that the polynucleotide molecule encodes the elements would obviate this rejection.

Claim 22 recites the limitation "said reporter moiety activity" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 5 indicates that the linker moiety is between about 1 to 30 amino acid residues while claim 27 indicates that the linker moiety is between about 1 to 30 amino acid residues while. It is noted that the base claims (1 and 23) indicate that the linker moiety comprises a protease cleavage site. Protease cleavage sites are comprised of more than 1 amino acid residue. Since the claims encompass linker moieties (i.e., protease cleavage sites) that are only 1 residue in size, the instant claims are indefinite. Applicants are asked to consider canceling claims 5 and 27 which would obviate this rejection.

Claim 3 indicates that the linker moiety is a non-naturally occurring polypeptide or protein. As indicated above, the linker moiety is defined by the base claim as being a protease cleavage site. It is unclear how a protease cleavage site (which are known to be naturally occurring proteins) could be a non-naturally occurring protein/polypeptide. Applicants are asked to consider canceling the claim, which would obviate this rejection.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 9, 11-31, 34-37 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the entire scope of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1 and 23 have been amended such that the claims are now are drawn to an in vitro method comprising providing a cell comprising a polynucleotide molecule comprising a destabilization domain a linker moiety and either a target or reporter moiety; however, the claims (i.e., claims 1, 23) still recite that each of the elements can be encoded by one or more nucleic acid molecules (see claim 1, lines 15-17; claim 23, lines 15-16). Therefore, the claims are NOT limited to a single nucleic acid molecule which encodes all of the elements in operable linkage.

Since the claims are not limited to a single nucleic acid molecule which encodes the elements, the claims are not fully enabled for the reasons previously indicated which are reiterated below.

It is noted that limiting the claims to a single nucleic acid molecule encoding the elements, for instance, by deleting the language the elements are encoded by one or more nucleic acid molecules would obviate this rejection.

Claims 1 and 23 are drawn to a method comprising providing a cell comprising at least one destabilization domain, a reporter moiety/target protein, and a linker moiety that operatively couples the destabilization domain(s) and the reporter moiety/target protein. It is noted that the claims indicate each of the elements (i.e., the destabilization domain(s), reporter moiety/target protein and linker domain) are encoded by one or more nucleic acid molecules in the cell. Based on the disclosure of the specification, one of skill in the art would only envisage the instant claims (claims 1, 23 as well as their dependent claims) as being drawn to a single polypeptide comprising the specific domains (e.g., the destabilization domain(s), the reporter moiety/target protein, and, the linker domain). It is noted that the claims indicate that the elements are operatively coupled. Furthermore, considering that the linker domain comprises a protease cleavage site when cleaved by a protease decreases the coupling of the destabilization domain(s) and the reporter/target protein the only reasonable use for these domains together is for either (1) detecting a protease activity, or (2) increasing the concentration of the target protein. Since the specification only appears to disclose the linker domain comprising a protease cleavage as part of a single polypeptide wherein the polypeptide comprises destabilization domain(s), the linker domain, and a reporter/target protein, and considering one of skill in the art would not reasonably envisage the three domains to work together as set forth in the claims when the three domains are

not expressed as a single polypeptide, the specification has not provided an enabling disclosure for the entire scope encompassed by the instant claims. Furthermore, one of skill in the art would not be able to predictably make and use the claimed invention when each of the elements is encoded by a different nucleic acid molecule such that all of the elements were operable linked. Specifically, the specification does not provide an enabling disclosure for the instant claims wherein the three domains are encoded by more than one nucleic acid molecule. Therefore, limiting claims 1, 23 and 38 to "a polynucleotide molecule" (and deleting the indication that the elements can be encoded by one or more nucleic acid molecules) would obviate this rejection.

It is acknowledged that the instant specification contemplates using the disclosed system to identify protein-protein interactions and also contemplates the linker can comprise protein interaction domains (such as SH1 or SH2 domains) such that the domains can be encoded by more than one polynucleotide sequences. However, the instant claims are specifically limited to the linker domain comprising a protease cleavage site such that the system can is useful for assaying protease activity or for increasing the concentration of the reporter/target protein. The only way one of skill in the art would understand the instant protease cleavage linker domain system to work would be when the system is expressed as a single polypeptide comprising the destabilization domain, linker and reporter/target protein.

It is noted that should claim 1 become limited to a single polynucleotide encoding all of the elements, as indicated above, claim 9 would be objected to because it would not further limit claim 1 because a single polynucleotide that encodes all of the operatively linked elements would necessarily indicate that the elements are covalently coupled together as indicated in claim 9.

Therefore, should applicants amend claim 1, as indicated above, they are asked to consider canceling claim 9 which would obviate this objection.

Response to Arguments

Applicant's arguments filed 6/7/2006 have been fully considered.

With respect to instant rejection of claims under 35 U.S.C. 112, first paragraph for not being fully enabled for the claimed invention wherein the domains/moieties can be encoded by "one or more nucleic acid molecules", Applicants arguments are not persuasive. Applicants argue that claims 83-86 have been cancelled, thus rendering the rejection based on these claims moot. It is acknowledged that the rejection as it pertains to the subject matter of cancelled claims 83-86 is now moot. Applicants also argue that claims 1 and 38 have been amended to limit the claims to "a polynucleotide molecule" as suggested by the Examiner. In response, it is respectfully pointed out that claims 1 and 23 have been amended to include the language "a polynucleotide molecule". However, the base claims (i.e., claims 1, 23) still recite that each of the elements can be encoded by one or more nucleic acid molecules (see claim 1, lines 15-17; claim 23, lines 15-16). Therefore, given the broadest reasonable interpretation, the claims are NOT limited to a single nucleic acid molecule which encodes all of the elements in operable linkage. Since the claims are not limited to a single nucleic acid molecule which encodes the elements, the claims are not fully enabled for the reasons indicated herein.

It is noted that limiting the claims to a single nucleic acid molecule encoding the elements, for instance, by deleting the language the elements are encoded by one or more nucleic acid molecules would obviate this rejection

Allowable Subject Matter

Claims 38, 50, 60 allowed.

Conclusion

It is noted that the instant Office Action contains rejections which were not necessitated by amendment (e.g., the lack of antecedent basis rejection, etc.). Accordingly this Action is made non-final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Mon-Fri, with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JON ANGELL
PATENT EXAMINER

J.E. Angell
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